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IN THE UNITED STATES PATENT & TRADEMARK OFFICE

In re: U.S. Patent No. 4,588,585 :
Issued: May 13, 1986 :
Inventors: David F. Mark : Box Pat. Ext.
Leo S. Lin :
Shi-Da Yu Lu :
For: HUMAN RECOMBINANT CYSTEINE :
DEPLETED INTERFERON- β MUTEINS :

CLARIFICATION OF APPLICATION
FOR EXTENSION OF PATENT TERM
UNDER 35 U.S.C. 1.56

Honorable Commissioner of
Patents and Trademarks
Washington, D.C. 20231

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SEP 27 1993

GROUP 2100

Sir:

The CAS registry number (90598-63-3) given at the bottom of page 2 of the extension request filed on September 9, 1993 is incorrect. The correct CAS registry number is 145155-23-3. Attached is a copy of the structures associated with each CAS number. As can be seen, the new number corresponds to a protein having the sequence of Betaseron® as given on page 3 of the request for extension.

With respect to item (9) of the extension request (see pages 5-8 thereof), the following clarifies certain aspects of claims 5 and 6 as well as claims 7-10 to the extent these depend on claims 5 and 6.

Claim 5: This claim is drawn to "Biologically active IFN- β_{ser17} ." That this nomenclature is used in the patent to refer to the sequence recited on page 3 of the extension request is clear from column 12, lines 3-7 and 18-21 thereof. These explicitly state that the sequence of IFN- β_{ser17} corresponds to the expected sequence predicted from the DNA sequence except for the absence of the N-terminal methionine


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residue, i.e., the Met residue in the 1-position. The latter is deleted from Betaseron® during processing in E. Coli as indicated in the footnote on page 3 of the extension request.

Claim 6: This claim is drawn to "IFN- β_{scr17} " as represented by the amino acid sequence represented in Fig. 10." Since the nomenclature "IFN- β_{scr17} " refers to the sequence recited on page 3 of the extension request, (1-Met deleted), as explained above with respect to claim 5, it is clear that the reference in claim 6 to Figure 10 is not meant to imply that the predicted amino acid sequence in Figure 10 (1-Met not deleted) is that of IFN- β_{scr17} . Rather, it is clear overall that the phraseology "represented by" and "represented in" used in claim 6 refers to the portions of Figure 10 which indeed do correspond to the actual sequence of IFN- β_{scr17} . The predicted 1-Met amino acid residue does not occur in the IFN- β_{scr17} protein which is actually produced in E. Coli because this first amino acid is cleaved during production as explained on page 3 of the extension request.

As a result, it can be seen that the statements of item (9) regarding coverage of Betaseron® by USP 4,588,585 are correct.

Respectfully submitted,



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